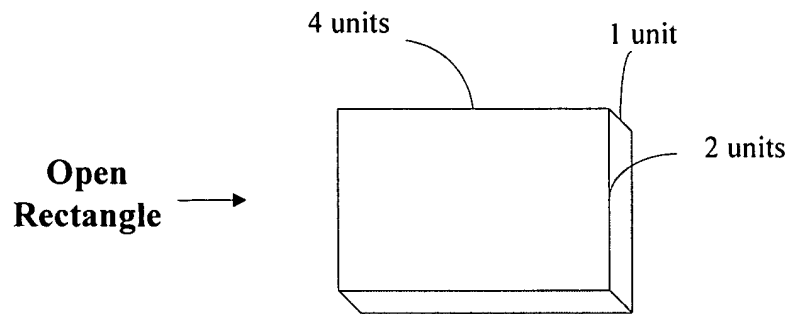


REMARKS

This responds to the Office Action dated 14 November 2005. Applicant respectfully requests reconsideration of the application based on the foregoing amendments and following remarks. Claims 20, 37, and 41 have been amended. New claim 42 has been added. Accordingly, claims 1-42 remain pending in the application. Applicant acknowledges the allowability of claims 4-14, 17, 18, 21, 23, 24, 26, 27, 29, 30, 32, 33, 35, 36, and 41. Applicant has amended claim 41 to put it in independent form. Therefore, the amendment to claim 41 is not a narrowing amendment, and thus it should retain its original scope.

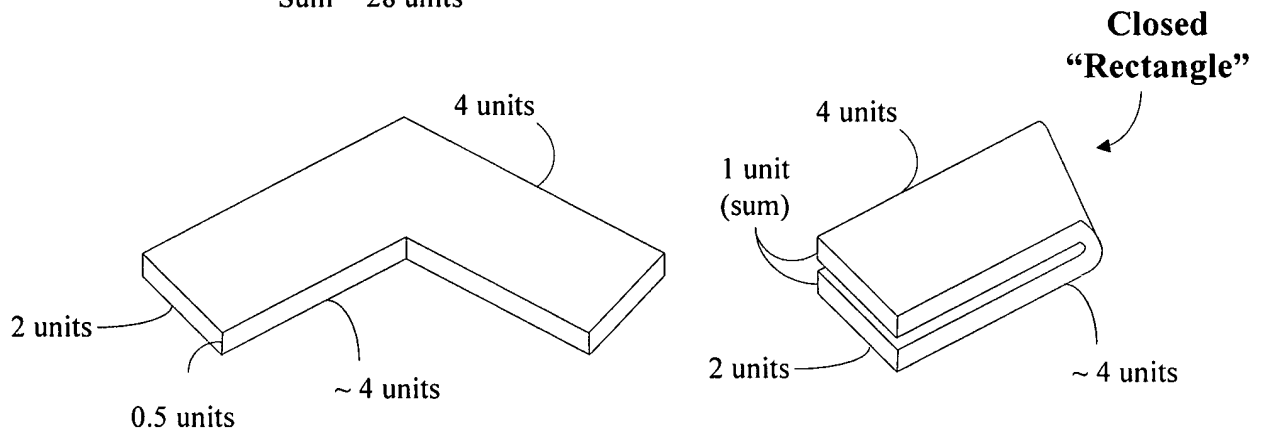
In the Specification

Applicant amended the third full paragraph on page 8 to correct minor mathematical errors. The surface area of a 4x2x1 rectangle was miscalculated. In addition, the surface area of the sealing plug 218 (FIGS. 2A-2B) was mistranscribed in one instance. These minor corrections are fully supported by the original disclosure. No new matter has been added to the disclosure by these minor corrections. The following illustrations show the correct calculations:



Surface Area
 $4 \times 2 \text{ (x 2 surfaces)} = 16$
 $4 \times 1 \text{ (x 2 surfaces)} = 8$
 $2 \times 1 \text{ (x 2 surfaces)} = 4$
Sum = 28 units²

Volume
 $4 \times 2 \times 1 = 8 \text{ units}^3$



Surface Area
 $4 \times 2 \text{ (x 4 surfaces)} = 32$
 $4 \times 0.5 \text{ (x 4 surfaces)} = 8$
 $2 \times 0.5 \text{ (x 2 surfaces)} = 2$
Sum = 42 units²

Volume
 $4 \times 2 \times 1 = 8 \text{ units}^3$

Applicant notes that the drawings are not to scale, but merely illustrative of the approximate surface area and volume calculations of an open rectangle and a generally V-shaped embodiment that may be folded to form a near-rectangle.

Claim Rejections – 35 U.S.C. § 112

The Examiner rejected claims 1-14 and 34-41 under 35 U.S.C. § 112, second paragraph, for failing to particularly point and distinctly claim the invention. Namely, the Examiner is uncertain how the surface-area-to-volume ratio is determined and what constitutes an “open” rectangle. Applicant has made a correction to the specification to eliminate any confusion.

An open rectangle is a rectangle that has not been folded or otherwise reshaped (*e.g.* the first illustration above). Therefore, the surface-area-to-volume ratio of an open rectangle is calculated by dividing the surface area of the rectangle by the volume of the rectangle. A minor mathematical error in the calculation of the surface area of a 4x2x1 rectangle was made in the specification, but has now been corrected. Some embodiments described in the specification include structures that may be folded or otherwise arranged to provide a greater surface area per unit volume than the surface areas of an open rectangle. With the correction to the specification, Applicant respectfully requests withdrawal of the rejection of claims 1-14 and 34-41 under 35 U.S.C. § 112, second paragraph.

Claim Rejections – 35 U.S.C. § 102(b) over Rousseau

The Examiner rejected claims 1-3, 15, 19, 20, 22, 25, and 28 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,425,924 to Rousseau. The Examiner contends that each element of the rejected claims is identically shown by Rousseau. Applicant respectfully traverses the rejection.

As the Examiner knows, every element of the claimed invention must be identically shown for a prior art reference to anticipate in terms of 35 U.S.C. § 102. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677 (Fed. Cir. 1988). Nevertheless, the rejected claims are not identically shown by Rousseau.

Claims 1, 25, and 28 each recite an anchor and a sealing plug. The Examiner cited a radially-expandable member 12 disclosed by Rousseau as the claimed sealing plug. The Examiner also alleged that the first and second conical members 14 comprising the sealing plug 12 constitute the claimed anchor. Applicant respectfully disagrees.

Rousseau states that his “[p]rosthesis 10 comprises radially-expandable member 12, comprising first and second conical members 14.” Col. 4, ll. 59-61. Moreover, the “[r]adially-expandable member 12 comprises conical members 14 fixedly attached one to the other at respective bases 20.” Col. 5, ll. 31-33. *See also* col. 5, ll. 9-10; col. 5, ll. 40-44. Although FIG. 1 of the Rousseau patent appears to show separate conical elements, the description to FIG. 1 recites “a perspective view of a prosthesis according to the present invention prior to assembly of all of its component parts.” Col. 2, ll. 20-22. Therefore, it is clear that the first and second conical members 14 comprise one unitary structure or “radially-expandable member 12.”

Logically, the same element cannot comprise both an anchor and a sealing plug. In addition, claims 1 and 28 of the present application recite “a sealing plug disposed proximal of the anchor.” The same element (Rousseau’s “radially-expandable member 12”) cannot be “disposed proximal” of itself. Therefore, Rousseau does not identically disclose both an anchor and a sealing plug disposed proximal of the anchor. Accordingly, Applicant

respectfully requests withdrawal of the rejection of claims 1, 25, and 28 under 35 U.S.C. § 102(b). Applicant also requests withdrawal of the rejection of all claims that depend from claims 1, 25, and 28.

Claim 25 includes additional limitations that are not anticipated by Rousseau as well. For example, claim 25 states that “the sealing plug comprises two cross members having a weave pattern through which the filament extends.” The Examiner pointed to the “radially-expandable member 12” and alleged that “the sealing plug comprises two cross members having a weave pattern.” However, Rousseau’s radially-expandable member 12 does not have two cross members, and the Examiner failed to identify any. Further, Rousseau does not disclose a “weave pattern” according to any reasonable definition of the term “pattern.” The Examiner did not establish a *prima facie* case of anticipation.

Similarly, claim 28 recites “first and second weave *patterns*” in the “first and second halves” of the “flexible sealing plug.” Rousseau does not disclose a flexible sealing plug. Rousseau does not disclose first (or second) weave patterns either. Therefore, the rejection of claims 25 and 28 under 35 U.S.C. § 102(b) should be withdrawn on these additional bases.

Claim 15 recites “an internal component...[and] a first external component...comprising at least one fold.” The Examiner identified Rousseau’s “first and second conical members 14” as the internal component and the “radially-expandable member 12” as the external component. As mentioned above, the same structure cannot comprise both an internal and an external component. Rousseau’s first and second conical members 14 and the radially-expandable member 12 are one and the same. Moreover, the

Rousseau radially-expandable member 12 is internal (or “posterior”), not external. Col. 6, ll. 26-34. Even if Rousseau did disclose an “external component,” it must also disclose a fold in the external component. However, Rousseau does not disclose an external component or a fold. Accordingly, Rousseau does not anticipate claim 15 and the rejection of claim 15 under 35 U.S.C. § 102(b) should be withdrawn.

All of the claims depending from claims 1, 15, 25, and 28 should also be allowable based on the arguments offered above. In addition, Applicant notes that Rousseau does not disclose a sealing plug “comprising at least two folds...wherein the at least two folds comprise an S-fold,” as recited in claim 3. Rousseau discloses pleats in the radially-expandable member 12, but does anticipate S-folds. Thus, claim 3 should be allowable for this additional reason.

Claim Rejections – 35 U.S.C. § 102(b) over Nash

The Examiner rejected claims 15 and 16 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,312,435 to Nash et al. (Nash). The Examiner contends that each element of the rejected claims is identically shown by Nash. Applicant respectfully traverses the rejection.

As mentioned above, every element of the claimed invention must be identically shown for a prior art reference to anticipate in terms of 35 U.S.C. § 102. The Examiner contends that Nash discloses an internal component 32, a first external component 28 which constitutes a collagen sponge, and a filament 30. However, the Examiner did not address the claim 15 recitation of an “external component comprising at least one fold.” The

Examiner has therefore failed to establish a *prima facie* case of anticipation. The sealing member 28 disclosed by Nash “comprises a compressed collagen or other hydrophilic resorbable material plug” and appears to be external. Nevertheless, there is no “fold” in the Nash sealing member 28 and therefore claim 15 is not anticipated.

Moreover, claim 16 recites “a stiff anchor,” while Nash appears to disclose a flexible anchor 32. FIG. 5 of Nash illustrates what happens to the flexible anchor 32 if it is subjected to forces applied by the filament 30. The flexible anchor 32 flexes and can be removed from a vessel. Therefore, Nash does not anticipate claims 15-16 and the rejection of claims 15-16 under 35 U.S.C. § 102(b) over Nash should be withdrawn

Claim Rejections – 35 U.S.C. § 102(e) over Akerfeldt

The Examiner rejected claims 31, 34, and 37-40 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,508,828 to Akerfeldt et al. (Akerfeldt). The Examiner alleges that each element of the rejected claims is identically shown by Akerfeldt. Applicant respectfully traverses the rejection.

As mentioned above, every element of the claimed invention must be identically shown for a prior art reference to anticipate in terms of 35 U.S.C. § 102. The Examiner contends that Akerfeldt discloses “a carrier tube (24) or insertion sheath, an anchor (2), a sealing plug (6) that is folded at least once or from a V-shape (fig. 18) into a substantially straight shape, and a filament (18).” However, Akerfeldt does not disclose a carrier tube.

The Examiner equates a carrier tube with an insertion sheath. Akerfeldt teaches an “introducer 24 (see FIG. 8),” but does not teach a carrier tube. Col 5, ll. 66. As claimed,

the carrier tube is part of “the tissue puncture closure device.” Further, as the name suggests, the carrier tube *carries* components of the tissue puncture closure device. The Akerfeldt introducer 24, on the other hand, does not carry anything. Akerfeldt makes clear that the introducer 24 is only an introducer, it is not a carrier tube *of the sealing device*. Akerfeldt is illustrative of the point:

FIG. 8 shows a **wound closer device**, which comprises the sealing device of any of the embodiments, mentioned above and a pusher 22 adapted for pushing the first sealing member 2, the elongated member 4 and the second sealing member 6 **through an introducer 24**.

The sealing device will be passed through the introducer 24 in order to reach its final position in the wound to be closed. To achieve this, the pusher 22 may be used to push the first sealing member 2, the elongated member 4 and the second sealing member 6 through the introducer 24.

Column 6, lines 9-18 (emphasis added). Clearly the introducer 24 taught by Akerfeldt is not part of the sealing device, the introducer 24 allows “the sealing device [to] be passed through.” In contrast, one embodiment disclosed in the present application illustrates a carrier tube 106 (FIG. 1B). Unlike an insertion sheath that only facilitates pass-through, the carrier tube 106 is *part of* the tissue puncture closure device and *carries* components thereof. The carrier tube 106 is not an insertion sheath. One embodiment of the carrier tube 106 is shown *inside* an insertion sheath 104 in FIG. 1B of the present application, further illustrating the difference between a carrier tube that is *part of* the tissue puncture closure device and an insertion sheath (which is all that is shown by Akerfeldt). Applicant notes that the embodiment of FIG. 1B is referenced to illustrate the distinction between an insertion sheath and a carrier tube, but FIG. 1B does not limit the claims. Accordingly,

Applicant respectfully requests withdrawal of the rejection of claim 31 under 35 U.S.C. § 102(e) over Akerfeldt.

Similarly, claim 34 specifically recites both an insertion sheath and a carrier tube. Akerfeldt, at most, discloses only an insertion sheath. Akerfeldt does not teach or suggest a carrier tube as part of the closure device and distinct from the insertion sheath. The rejection of claims 34 is improper. Accordingly, Applicant respectfully requests withdrawal of the rejection of claim 34 under 35 U.S.C. § 102(e) over Akerfeldt.

Amended claim 37 recites, *inter alia*, “filling the internal tissue puncture with the sealing plug.” Akerfeldt, on the other hand, discloses sealing members 2, 6 that can cover a puncture, but do not fill the puncture. In addition, it does not appear that the Akerfeldt sealing members 2, 6 have “a higher surface-area-to-volume ratio than an open rectangle for a given set of rectangular dimensions.” Therefore, claims 37-40 should be allowable.

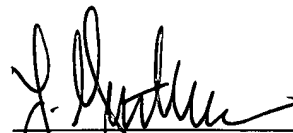
CONCLUSION

Applicant respectfully submits that all claims should now be in condition for allowance. If there are any matters that have yet to be resolved in connection with the present application, Applicant respectfully requests the Examiner to telephone the undersigned attorney to expedite the handling of this application.

Respectfully submitted,

Date:

14 FEBRUARY 2006



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